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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,320	03/05/2001	Volker Hinz	BAYER 10 218	7238

7590 01/02/2004

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New York, NY 10017

EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT PAPER NUMBER

1624

DATE MAILED: 01/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/719,320

Applicant(s)

HINZ ET AL.

Examiner

Venkataram Balasubramanian

Art Unit

1624

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED \_\_\_\_\_ FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☒ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attached Advisory Action.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: \_\_\_\_\_.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☒ Other: See attached Advisory Action

### **ADVISORY ACTION**

The amendment filed 12/10/2003 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance for the following reasons.

First of all, page 4 of the current response is missing and therefore it is not possible to examine claim 1 fully. Applicants should also note that examiner had indicated in the previous office action, claim 1 is incomplete and hence had maintained all 102/103 rejections.

Again in view of missing part of the claim 1, it is not possible address whether all prior art 102/103 rejections were obviated or not.

Hence, all prior art 102/ 103 rejections made in the previous office action are maintained.

In response to this advisory action, applicants are requested to check claim 1 for its completeness.

Applicants should also note that, as stated in the previous office action, pending claims were examined to the extent they embrace the elected subject matter.

The following 112 rejection made in the previous office action is also maintained.

### ***Claim Rejections - 35 USC § 112***

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating cerebral diseases, does not reasonably provide enablement for prevention of cerebral diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly

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connected, to use the invention commensurate in scope with these claims for reasons of record.

This rejection is same as made in the previous office action. In response to this rejection, applicants have provided a declaration to support prevention of cerebral disease. However, the declaration is not persuasive.

1. First of all, the declaration does not lend support to prevention any or all cerebral diseases.
2. As noted in the previous office action, "To prevent" actually means *to anticipate or counter in advance, to keep from happening etc.* (as per Webster's II Dictionary) and there is no disclosure as to how one skilled in the art can reasonably establish the basis and the type of subject to which the instant compounds can be administered in order to have the "prevention" effect. There is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with cerebral diseases claimed herein. The declaration fails to address this issue.
3. The declaration appears to be limited to treating injury-induced edema due to intracranial pressure as there is no suggestion or teaching how would one know who is to have such an injury-induced edema in advance.

Hence this rejection is maintained.

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Art Unit: 1624

### **Conclusion**

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (703) 308-4716. The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
V. Balasubramanian

12/29/2003

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